

**SEATTLE CHILDREN'S RESEARCH INSTITUTE  
OPERATING POLICIES / PROCEDURES**

<b>DEPARTMENT:</b>	Institutional Animal Care and Use Committee
<b>POLICY NUMBER:</b>	IACUC-012
<b>REPLACES:</b>	
<b>EFFECTIVE DATE:</b>	June 10, 2005
<b>REVISION DATE:</b>	March 7, 2011
<b>POSTED FROM:</b>	

**TITLE:** Evaluation Of Animal Care And Use Concerns

**SUMMARY:**

The purpose of this policy is to describe how animal care and use concerns will be addressed to ensure that laboratory animals receive humane care and are used in research in accordance with the highest ethical standards, laws, regulations and policies governing animal research.

**POLICY/PROCEDURE:**

- 012-1 Seattle Children's Research Institute (SCRI) will create an environment that promotes compliance with ethical standards and laws, regulations, and policies governing animal research by:
- 012-1.1 Continually emphasizing that compliance is important for both ethical and legal reasons in training and orientation sessions;
  - 012-1.2 Maintaining efficient administrative procedures for review of protocols, amendments to approved animal protocols, and self-reporting of apparent departures from approved procedures;
  - 012-1.3 Facilitating communication of animal care and use concerns;
  - 012-1.4 Strict adherence to policies for review and disposition of animal care and use concerns.
- 012-2 Communication of animal care and use concerns to the Institutional Animal Care and Use Committee (IACUC).
- 012-2.1 Concerns regarding institutional animal care and use may be reported anonymously to the IACUC via the Office of Animal Care (OAC) or directly to any member of the IACUC verbally or in writing;

012-2.2 Regardless of the source, method of conveyance, or person to whom the complaint is conveyed, all concerns will be reported to the IACUC Chairperson immediately. Complainants should be asked to do so directly. If they are unwilling to do so, the person to whom the complaint is conveyed is responsible for forwarding the complaint to the IACUC Chairperson.

012-2.3 The confidentiality of those who report concerns and those against whom allegations are directed will be strictly maintained while allegations are under investigation. Any employee of SCRI, or other complainant, can report deficiencies in animal care and treatment without fear of retribution or reprisal.

012-3 IACUC review and disposition of animal use concerns.

012-3.1 Initial Evaluation

012-3.1.1 The IACUC Chairperson will act immediately to determine if the complaint has any merit by interviewing persons involved and reviewing any necessary records. The guiding principles in the evaluation of a complaint throughout this process are: 1) to determine if procedures are being used that have not been approved by the IACUC, and 2) to clarify whether any unapproved activities adversely affect the health or well-being of either research animals or humans. If this initial evaluation determines that the complaint has no merit on either of these counts, no action will be taken and a report of the incident will be recorded in the minutes of the next IACUC meeting. If the complaint is determined to have merit, or if lack of merit cannot be established, the IACUC will be convened to further assess the complaint. In any case, where initial investigation indicates that immediate action is required (see below), the IACUC will be convened immediately (within 24 hours) even if a quorum is not available. If immediate action is not indicated, the IACUC will convene as soon as possible. In cases where the IACUC Chairperson may have a conflict of interest, the Institutional Official (IO) shall appoint another member of the IACUC to assure that the concern is addressed.

012-3.2 Initial Committee Actions

012-3.2.1 The IACUC will determine if the complaint requires:

012.3.2.1.1 Immediate Action And Further Investigation

Immediate action is required if either animal or human health or well-being is endangered. If

immediate action is deemed necessary, the IACUC Chairperson will notify the IO to decide what further course of action should be taken. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate health or safety officials will be considered. If an activity is suspended, the IO will report that action to the appropriate regulatory and funding agencies, including the Office of Laboratory Animal Welfare (OLAW). Further investigation by the IACUC and completion of a report will be necessary as described below.

#### 012.3.2.1.2 Further Investigation Without Immediate Action

If further investigation with or without immediate action is required as determined by the IACUC, the IACUC Chairperson, his/her designee, or an IACUC subcommittee, will conduct the investigation and report back to the IACUC. All actual or perceived conflict of interest will be avoided. The information required by the IACUC (e.g. who to interview, observation of animals, reviewing records, and a deadline) will be established and recorded in the minutes of the meeting. The deadline established will depend on the IACUC's determination of whether or not additional action may be required to protect animal or human health or well-being. The investigative report to the committee will include a description of the concern, results of interviews, reference to the condition of animals and environment, results of records reviewed, and any supporting documents. The report must include conclusions regarding the substance of the concern and recommended actions.

#### 012.3.2.1.3 No Action

If no action is deemed warranted, the incident will be reported in the minutes of the next IACUC meeting.

### 012-3.3 Final Committee Actions

012-3.3.1 Upon receipt and review of the report of the investigation, the IACUC may request further information or find that:

012.3.3.1.1 There was no evidence to support the complaint;

012.3.3.1.2 The complaint was not sustained but other issues regarding animal care and use require further review, or;

012.3.3.1.3 The complaint was valid.

### 012-4 IACUC Reporting

012-4.1 It is the responsibility of the IACUC to carefully and comprehensively evaluate all animal care and use concerns and to produce and record a report of their deliberations. The final report will include an assessment of how the IACUC or administration can act to prevent similar reoccurrences, and any recommendations to the IO regarding possible sanctions.

### 012-5 Subsequent actions by the IACUC may include:

012-5.1 Implementing measures to prevent reoccurrence (i.e., changes in administrative, management, or IACUC policies and procedures);

012-5.2 Notifying the IO and the Attending Veterinarian of its actions;

012-5.3 Notifying funding or regulatory agencies as required;

012-5.4 Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials;

012-5.5 The IO is responsible for:

012-5.5.1 determining what sanctions, if any, will be imposed based on the IACUC's recommendations, and;

012-5.5.2 implementing any imposed sanctions.

012-5.6 Sanctions may include:

012-5.6.1 counseling;

012-5.6.2 additional training to prevent future incidents;

012-5.6.3 monitoring of research activities by the IACUC or IACUC-appointed individuals;

012-5.6.4 letters of reprimand;

- 012-5.6.5 temporary revocation of animal-related research privileges pending compliance with specific IACUC-mandated conditions;
- 012-5.6.6 permanent revocation of animal-related research privileges, and/or;
- 012-5.6.7 other institutional sanctions.

## REFERENCES

ARENA / OLAW, "The Institutional Animal Care and Use Committee Guidebook", 2<sup>nd</sup> Ed. NIH. Bethesda, MD. 2002

Submitting Office: Office of Institutional Assurances

Approved by:

\s\ Anne Clancy, IACUC Chairperson, 3/24/2011

\s\ William R. Morton, VMD, Attending Veterinarian, 3/30/2011

\s\ Mason Craig Bailey, Manager/Office of Animal Care, 3/24/2011